UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,545	11/15/2001	Herve Fridman	SF0941K	5775

7590 04/06/2006

Cynthia L Foulke
Patent Department K 6 1 1990
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530

EXAMINER	
XIE, XIAOZHEN	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,545	FRIDMAN ET AL.	
	Examiner	Art Unit	
	Xiaozhen Xie	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *4-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20020539.20060223*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The Information Disclosure Statement (IDS) filed 30 May 2002 and 23 February 2006 has been entered. Applicant's amendments of the specification filed 15 November 2001, 22 July 2002 and 9 June 2003 are acknowledged.

Election/Restriction

Applicant's election of Group I, claims 1-4, and species IL-17 in the reply filed on 23 February 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 4-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-9 are pending. Claims 1-3 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a method of suppressing tumor proliferation in a mammal comprising administering an IL-17 or an IL-17 antagonist in an amount effective to suppress proliferation of tumor cells. What applicant has described in the specification are human IL-17 and antibody that specifically binds to the IL-17. Applicant has not described other IL-17s, nor other IL-17 antagonists which inhibit the receptor binding. There is no teaching regarding the relationship of structure to function, such as what structure features are required for an inhibition of the binding between IL-17R and IL-17. Further, the specification also does not disclose a representative number of species of IL-17 commensurate with the scope of the genus of IL-17 recited in claim 1 (fish IL-17, chicken IL-17, etc.). Thus, the claims encompass a genus of molecules, which vary substantially in composition, and could have very different structural and functional characteristics from the polypeptide that Applicant has disclosed.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making of the claimed product, or any combination thereof. In this case, there is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient

recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of peptides, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that is part of the invention and reference to a method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only human IL-17, or an antibody that specifically binds to the human IL-17, but not the full scope of the claimed IL-17s, IL-17 antagonists, are adequately described in the disclosure.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of suppressing tumor cell proliferation in a mammal affiliated with the tumor, wherein the tumor cells have IL-17 receptors, comprising administering to the subject an anti-huIL-17 antibody, does not reasonably provide enablement for administering to any subject including normal individual or other mammal IL-17 or any IL-17 antagonists. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claims are directed to a method of suppressing tumor proliferation in a mammal comprising administering an IL-17 or an IL-17 antagonist in an amount effective to suppress proliferation of tumor cells. The claims are broad in that they encompass or require the use of a full-length huIL-17, or any IL-17 antagonists in any subjects with any type of tumors and in individuals without a disease. The specification discloses an anti-huIL-17 antibody, which can block the ligand binding to the receptor, and inhibit tumor cell proliferation in vivo. The specification, however, does not provide any guidance for suppressing tumor cell proliferation using a full length huIL-17, nor provide any guidance for making or using other IL-17 antagonists that have the same properties as the anti-IL-17 antibody. Numasaki et al. (J. Immunol., 2005, Vol. 175, pp. 6177-6189) teach that IL-17 enhances in vivo growth of human non-small cell lung cancer in SCID mice (Abstract, and pp. 6183, Figure 6). The specification also shows the similar pro-tumor growth effect for IL-17 (pp. 15, Example 3). Since there is no

guidance in the specification as to how to use a full-length IL-17 to inhibit tumor cell proliferation in a mammal, one of skill in the art would resort to undue experimentation to determine whether or how the claimed invention can be practiced. Also, there is no sufficient teaching in the specification regarding the relationship of structure to function for all IL-17 antagonists, such as what structure features are required for a molecule to be able to inhibit the binding between IL-17R and IL-17. It is well known in the art that anti-cytokine agents include a wide variety of molecules, such as antibodies, soluble cytokine receptors, cytokine receptor antagonists, cytokine-Fc fusions, counter-regulatory cytokines, and naturally occurring cytokine inhibitors (Taylor, Curr. Pharm. Design, 2003, Vol. 9, pp. 1095-1106). Not all of the anti-cytokine agents can be used for treatment of diseases. For example, Sehouli et al. (Anticancer Res., 2002, Vol. 22(6A), pp. 3421-4) teach that IL-1 receptor antagonist polymorphism is associated with increased risk of developing cancer (pp. 3421, Abstract). Further, The specification does not teach how to treat tumors without the IL-17 receptors, nor to treat any other diseases, nor to treat individuals without tumor. There is no limitation on the disease or patient population to be treated or prevented.

Since the specification does not define the structures for all IL-17 antagonists, and fails to define patient population, one of skill in the art would evaluate all non-exemplified IL-17 and IL-17 antagonists for inhibition of tumor cell proliferation in any individual with or without the disease. The scope of patent protection sought by Applicant as defined by the claims fails to correlate reasonably with the scope of enabling disclosure set forth in the specification.

Due to the large quantity of experimentation necessary to generate the nearly infinite number of IL-17 antagonists recited in the claims and screen same for inhibition of tumor cell proliferation in any subject, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of anti-cytokine agents in human, and the breadth of the claims which fails to recite any structural limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: there is no patient population to whom the drug is administered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Tartour et al. (Proc. Am. Assoc. Cancer Res., 1998, March, pp. 653, Abstract # 4447). Tartour et al. teach an inhibition of cervical tumor cell growth by administering an anti-IL-17 antibody in nude mice. Therefore, Tartour et al. anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tartour et al., in view of Jacobs et al. (WO 97/04097, 6 February 1997).

Tartour et al. teach as set forth above, a method of inhibiting tumor cell growth by administering an anti-IL-17 antibody in nude mice. Tartour et al., however, does not teach applying the method to human, and using a monoclonal antibody. WO 97/04097 teaches that monoclonal antibodies binding to human CTLA-8 protein (IL-17) may be useful therapeutics for certain tumors. WO 97/04097 teaches that these monoclonal antibodies are capable of blocking binding to the human CTLA-8 (pp. 20, lines 5-21).

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to combine the teachings of Tartour et al., with those of WO

97/04097 to use an anti-IL-17 monoclonal antibody to inhibit tumor cell proliferation in humans. One of ordinary skill in the art would have been motivated to combine the teachings, because Tartour et al. teach an inhibitory effect of anti-Il-17 antibody on tumor cell growth, and WO 97/04097 teaches such monoclonal antibodies and their usefulness in treating certain tumors in humans. Therefore, the combined teachings provide a reasonable expectation of successfully treating cancer in humans.

Claim Objections

Claim 1 is objected to because of the following informalities: it recites non-elected inventions. Appropriate correction is required.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie, Ph.D whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph.D. can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

Xiaozhen Xie, Ph. D.
March 29, 2006